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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,881

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Koetsu Saito

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10/24/2008

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MINNEAPOLIS, MN 55402

EXAMINER

BOR, HELENE CATHERINE

ART UNIT

PAPER NUMBER

3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,881	Applicant(s) SAITO, KOETSU	
	Examiner HELENE BOR	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>NPL, Search Notes & Foreign Patent w/ English Abstract.</u> |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claim 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okunuki et al. (US Patent No. 5,460,179), and further in view of Kanebo (JP 61149128; enclosed herein).

Claim 1-6 & 8-10: Okunuki teaches an ultrasonic probe comprising an ultrasonic transducing part for transmitting and receiving an ultrasonic wave (Col. 3, Line 2-14); an outer case for storing the ultrasonic transducing part (Figure 3, Element 24) and an acoustic medium charged in the outer case (Figure 3, Element 60). Okunuki teaches an ultrasonic probe for oscillating or rotating the ultrasonic transducing part (Col. 3, Line 9-14). Okunuki teaches wherein the ultrasonic transducing part includes an array element in which a plurality of transducers are arranged (Col. 4, Line 45-50). Okunuki teaches wherein the outer case includes an ultrasonic wave propagation window (Figure 3, Element 24A). Okunuki teaches that the acoustic medium is a liquid whose acoustic impedance is roughly equal to that of a living body (Col. 8, Line 6-11 & 26-30) but not 1,2-butylene glycol or 1,3-butylene glycol in particular. Kanebo teaches a viscous composition for ultrasonic diagnosis consisting of 1,3-butylene glycol and water with a 60-85% weight for good energy propagation (Abstract). Kanebo teaches other chemical soluble with 1,3-butylene glycol [such as water and a polyhydric alcohol] (Abstract). It would have been obvious to modify the acoustic medium of Okunuki to include the 1,3-

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butylene glycol as taught by Kanebo because 1,3-butylene glycol can keep propagation of ultrasound energy good and has excellent storage stability (Abstract). Kanebo does not specifically mention 1,2-butylene glycol. However according to Miller (Miller, L.M. "Investigation of selected potential environmental contaminants: ethylene glycols, propylene glycols and butylenes glycols: Final Report". Franklin Research Center, Philadelphia, PA. 01 May 1979. PB-80-109119), butylene glycol has four isomers, 1,3-, 1,4- 2,3- and 1,2-butylene glycol. It would have been obvious for one of ordinary skill in the art to substitute one of the four butylenes glycol known isomers for another in order to achieve the predictable result of a medium suitable for ultrasonic transmission.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okunuki et al. (US Patent No. 5,460,179), and Kanebo (JP 61149128) as applied above to 1-6 & 8-10 and further in view of Ludwig (Ludwig, George. *The Velocity of Sound through Tissues and the Acoustic Impedance of Tissues*. The Journal of the Acoustical Society of America, Nov 1950: (22)(6) 862-866; included in the Last Office Action) and in view of Schafer (Schafer, Mark E et al. *Use of Time Delay Spectrometry in Fluid Attenuation Measurement* Ultrasonics Symposium, 1989: 973-976; included in the last Office Action).

Claim 7: Okunuki teaches that the acoustic medium is a liquid whose acoustic impedance is roughly equal to that of a living body [room temperature inherent] (Col. 8, Line 6-11 & 26-30) and produces an ultrasound at a frequency of 3 MHz (Col. 2, Line 25-29). Okunuki does not teach the range of acoustic impedance. However, Ludwig defines the acoustic impedance of human tissue as 1.58-1.70 Mrayl [converted value]

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and that 1.63 Mrayl is the average value of human tissue (Page 865, Table I). One of ordinary skill in the art at the time of the invention would have understood the definition of human tissue impedance and would have understood that fluids having an acoustic impedance within the defined range as taught by Ludwig would have been desirable within the system of Okunuki. Okunuki fails to teach the acoustic medium having an attenuation of 0.07 to 0.091 dB/mm. However, Schafer provides the acoustic attenuation properties for 1,3 Butylene Glycol (Page 976, Figure 3) for providing information to manufactures to chose the ideal fluid (Page 973, Part I). It would have been obvious for one of ordinary skill in the art to understand the attenuation properties of fluids as taught by Schafer and to modify the system of Okunuki and Kanebo to include the desired fluid as taught by Schafer in order to chose the ideal fluid (Page 973, Part I).

Response to Arguments

Applicant's arguments, see Page 2, filed 06/18/2008, with respect to the rejection(s) of claim(s) 1-10 under Buon (US Patent No. 4,494,548) and further in view of Nonomura (US Patent No. 7,001,355 B2) have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Okunuki et al. (US Patent No. 5,460,179), and further in view of Kanebo (JP 61149128). The previous rejection was withdrawn and a new one applied. In relation to 1,2-butylene glycol and 1,3-butylene glycol the argument is similar to one the one in the previous rejection and will be addressed herein. The Applicant submitted the argument that it would not be obvious to one of

ordinary skill in the art to try one isomer for the other in order to achieve a predictable result. The Applicant presents the difference in viscosity between 1,2-butylene glycol and 1,3-butylene glycol. The Examiner respectfully disagrees. Hawrylak'27 (Journal of Solution chemistry, Vol. 27, No. 9, 1998; referenced to herein as Hawrylak'27) does show that 1,2-butylene glycol is less viscous than 1,3-butylene glycol in Table I but Schafer explains how more viscous fluids generally show higher levels of attenuation (Page 975, Part V). In light of the art, one of ordinary skill in the art would be looking for a less viscous fluids as 1,2-butylene glycol and would expect the desirable result of less attenuation of the ultrasound. Applicant presented the argument that the general assumption presented by Schafer does not hold in every situation and therefore it would not be obvious to one of ordinary skill in the art. The Examiner respectfully disagrees. Schafer states, "The more viscous fluids **generally** showed higher levels of attenuation" (Page 975, Part V). Schafer states a general statement to explain the trend between viscosity and attenuation. It would have been obvious to one of ordinary skill in the art to understand what would be an expected or predictable result from going from the more viscous 1,3-butylene glycol to the less viscous 1,2-butylene glycol which is less attenuation. This relationship is supported by the Applicant's Figures 2 & 3 in which the less viscous 1,2-butylene glycol produces less attenuation than 1,3-butylene glycol. 1,2-butylene glycol has not produced an unexpected result from the general rule as explained by Schafer. Although the Applicant submitted other substances that produced unexpected results, the Applicant has not produced satisfactory evidence as to why 1,2-butylene glycol produces unexpected results. The Applicant submitted that

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there was the unexpected result that 1,2-butylene glycol was about equal to the acoustic impedance of tissue. The Examiner respectfully disagrees. The equation for acoustic impedance is known in the art as:

$$Z = \rho \cdot c$$

Wherein Z = acoustic impedance (MRayl; $\text{kg} \cdot \text{m}^{-2} \cdot \text{s}^{-1}$), ρ = density ($\text{kg} \cdot \text{m}^{-3}$) and c = propagation speed (m/s)¹. Using the established equation with the art and using the data provided by Hawrylak'76 (Table I), one of ordinary skill in the art without any undue experimentation can calculate the acoustic impedance of 1,2-butylene glycol to determine if the acoustic impedance of 1,2-butylene glycol roughly matched the acoustic impedance of tissue.

$$0.99990 \text{g} \cdot \text{cm}^{-3} \times 1453.0 \text{m} \cdot \text{s}^{-1} = Z$$

Convert the units

$$0.99990 \text{g} \cdot \text{cm}^{-3} \times \frac{1 \text{g} \cdot 100^3 \text{cm}^3}{1000 \text{kg} \cdot \text{m}} = 999.9 \text{kg} \cdot \text{m}^{-3}$$

$$999.9 \text{kg} \cdot \text{m}^{-3} \times 1453.0 \text{m} \cdot \text{s}^{-1} \times \frac{1}{10^6} = 1.45 \text{MRayl}$$

Okunuki teaches the importance of having an acoustic medium in the device that is roughly equal to that of human tissue. Given the simple calculation is all that is needed with known equations and data in the art, it would have been obvious to one of ordinary skill to try 1,2-butylene (as an isomer of 1,3-butylene glycol) and expect the result that its lower viscosity would result in lower attenuation. Further that one of ordinary skill in the art would find 1,2-butylene glycol would be a desirable obvious choice with its

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similar acoustic impedance to tissue which can be calculated easily with the known equations and data collected within the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768

¹ Anderson, Bonita. Echocardiography: The Normal Examination and Echocardiographic Measurements. Blackwell Publishing, 2000. [ISBN 0646391399, 9780646391397] (Page 4 is enclosed herein).

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